IN THE DRAWINGS:

Applicants hereby submit a replacement sheet for drawing sheet 1 (Figures 1-3), enclosed herewith. In Figure 1 of the replacement sheet, reference numeral "16" has been corrected to indicate that the inner end of the access member is --1b--. Entry of the replacement sheet is requested.

REMARKS

The Office Action mailed July 27, 2004, has been carefully reviewed and Applicants note with appreciation the Examiner's identification of allowable subject matter.

By this Amendment, Applicants have amended claims 1-18 and added claims 19 and 20. Claims 1-20 are pending in the application. Claims 1, 17 and 18 are independent.

As an initial matter, upon reviewing the Office Action Summary page of the outstanding Action, and particularly item 12 thereof, Applicants request that the Examiner provide acknowledgment of Applicants' claim for foreign priority and receipt of the priority documents. The status of Applicants' drawing submission is also requested.

The Examiner objected to the abstract and the disclosure as containing informalities which Applicants have corrected herein. A replacement abstract incorporating the amendments set forth herein has also been provided on a separate sheet.

Applicants have also provided herewith a replacement sheet for Figures 1-3 in which reference numeral "16" of Figure 1 has been corrected to read --1b--.

With respect to the claim rejections, as there are discrepancies between the Disposition of Claims statement (items 5

and 6) on the Summary page of the Office Action and the subsequent Detailed Action, Applicants have proceeded on the basis of the Detailed Action.

The Examiner rejected claims 1-3, 5 and 17 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,417,666 to Coulter. Under 35 U.S.C. 103(a), the Examiner rejected claims 4 and 18 as being unpatentable over Coulter, and rejected claims 12-16 as being unpatentable over Coulter in view of U.S. Patent No. 5,704,353 to Kalb et al. ("Kalb"). The Examiner objected to claims 6-11 as being dependent on a rejected base claim but stated that claims 6-11 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

While Applicants appreciate the identification of allowable subject matter in claims 6-11, with the clarifying amendments presented herein Applicants submit claims 1, 17 and 18 as also being in condition for allowance and provide the following remarks in support thereof.

As set forth in each of claims 1, 17 and 18 as amended herein, the present invention is directed to an access member, a system for catheterization using the access member, and a method of changing the access member. The access member has inner and outer

ends that define a predetermined length which extends *from the outside of the body of the user to, and into, the urinary bladder*. The wall of the access member defines at least one cavity for receiving a catheter, the cavity extending substantially throughout the predetermined length. The wall is sufficiently flexible that, when a catheter is not inserted in the access member, i.e., between catheterizations, the cavity is kept in a substantially closed position by the mutual contact of parts of the wall. Hence, the access member may be comfortably worn by the user in between catheterizations, the sealing effect of the walls preventing the leakage of urine from and the entry of water to the access member (see page 5, lines 1-14). This is not shown or suggested by Coulter, such that each of claims 1, 17 and 18 is patentable thereover.

Coulter discloses a semi-rigid funnel member 4 and a flexible cover member 5 which are inserted into the lower portion of the urethra prior to catheterization. As discussed at column 5, lines 22-32, the length of these two members is related to the length of the contaminated area 13, the latter being defined at column 1, lines 33-34 and 43-47. In short, the purpose of Coulter is to provide a sterile shield for a catheter that prevents bacteria in the contaminated area from being carried into the

bladder by the catheter as it is inserted. Hence, in no way does either the funnel member 4 or the cover member 5, or any other part of the shield, extend *into the bladder* as this would negate the intended function of Coulter. Rather, the specific dimensions provided at column 5, lines 28-32, for the length of the funnel member for male and female use are far less than the typical lengths of the respective urethras themselves. For example, the described dimension for female use is less than half the length of a typical female urethra but is a dimension that is fully in line with the description of the contaminated area as being limited to the lower zone, i.e., near the outer end, of the urethra.

As just summarized, there is nothing in Coulter to suggest an access member that extends from outside the patient's body through a canal, whether natural or artificial, into the bladder and for this reason alone the present invention as set forth in claims 1, 17 and 18 is patentable over Coulter.

In addition, Applicants note that the combination of a semi-rigid funnel member 4 and a removable, flexible cover member 5 which are placed in the outer area of the urethra is central to the device disclosed by Coulter. There is no indication that Coulter contemplated using either of these members in isolation in

the manner in which the access member of the present invention is worn by the patient between intermittent catheterizations.

Furthermore, the funnel member 4 of Coulter which, after removal of the cover member 5 (column 5, lines 15-19) is the only member remaining in position for introduction of a catheter, is clearly described in column 4, line 29, and column 5, line 56, as being "semi-rigid". As used in the text just cited and defined at column 7, lines 18-20, this terminology at least suggests that contact between parts of the wall of the funnel member is neither foreseen nor possible. Particularly, it would appear that the funnel member would require sufficient rigidity to not only retain an open bore 10 for catheter insertion but also to provide shape integrity during the cover removal process (see column 4, line 67 to column 5, line 19). Were the funnel member flexible like the cover member (see column 2, line 67 to column 3, line 1, where the funnel is described as "semi-rigid" while the cover member is "flexible"), the necessary removal of the cover member prior to catheter insertion would also remove or misalign the positioning of the funnel member.

Nor would there be any reason for the walls of the funnel member to be sufficiently flexible so as to be sealed against one another when a catheter is not inserted because the funnel member

of Coulter is not retained within the patient's urethra once catheterization is complete. Instead, such flexibility could only complicate the cover removal and catheter insertion procedures. Hence, a person of ordinary skill in the art would find no motivation to modify Coulter to include an access member having a wall that is sufficiently flexible so as to, in response to forces imposed by surrounding tissues, seal the access member through contact of the wall portions with one another in the manner set forth in claims 1, 17 and 18 of the present invention.

For at least the foregoing reasons, claims 1, 17 and 18 are patentable over the prior art. Claims 2-16, 19 and 20 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein, particularly that of claims 6-11 as identified by the Examiner.

Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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ABSTRACT

An access member for use in catheterization having an outer end and an inner end. The access member, which is adapted to extend from the outside of the body through a canal extending from the user's abdominal wall to the bladder and into the bladder, has at least one cavity extending substantially throughout the length of the access member. The walls of the access member are made from a flexible material such that the cavity is generally kept closed by the mutual contact of the walls while allowing for intermittent insertion of a catheter.